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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,051	04/26/2001	Martin T. Gerber	P-8436.03CIP1	8909
27581	7590	03/15/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,051	GERBER ET AL.	
	Examiner George R Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/19/05 has been entered.

Election/Restrictions

Claims 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed 2/20/03. In addition, claim 21 is withdrawn from consideration due to an election by original presentation made in the office action of 10/19/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 8, and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaer (6251107). Schaer provides a flexible coil electrode that can be intravascularly

positioned and is therefore capable of meeting the functional use recitations presented in the claims. In addition, element 34 is considered to be the electrode connector since it is both coupled/connected/adhered to the coil electrode and conductor. Also, any of the other coil electrodes can be considered to be the claimed “ring shaped electrode” located proximal or distal to a coil electrode. Finally, for claims 8 and 10, Schaer shows in figure 3 the connector having “substantially” common outer diameters.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Speicher et al (4603705). Speicher is capable of meeting the functional use recitations presented in the claims since he use an implantable, flexible coil electrode. In addition, Speicher meets the claimed limitation of “about

Art Unit: 3762

2 mm" since his coil diameter is "about 3 mm" (col 5). Also, Speicher shows the electrode connectors (20, 22, 50, or 52) connected to one another in connection zones or adhered to (dictionary definition of adhered of "to give support" or "to hold fast or stick by") since the coil electrode and connector are maintained in connection with each other to provide the implantable lead. Finally, Speicher show the ring shaped electrode as the other coiled electrode or conductive electrode connectors 20, 22, 50, or 52.

In the alternative, Speicher discloses the claimed invention except for the coil diameter being from about 0.5 mm to about 2.0 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with a coiled electrode having a diameter of about 0.5 mm to about 2.0 mm since it was known in the art that implantable leads with coil electrodes use a coil electrode of about 0.5 mm to about 2.0 mm to provide an implantable lead having a coil electrode that is small and unobtrusive. In addition, one skilled in the art would have expected both the applicants claimed invention and Speicher's invention to have the same properties even though the ranges do not overlap since both are used for providing an implantable lead with flexible coiled electrodes. (According to MPEP 2144.05, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties).

Claims 3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speicher et al.

Speicher discloses the claimed invention except for the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with the electrode and connector being butt-welded together since it was known in the art that implantable leads use a butt-weld to connect electrodes and connectors to provide a secure and easily produced connection to connect the two elements together.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the implantable lead as taught by Speicher with the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters, because Applicant has not disclosed that the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode connector and coil electrode being connected together and the inner diameters not being substantially the same as taught by Speicher, because Speicher provides a coil electrode and connector that is flexible and implantable.

Therefore, it would have been an obvious matter of design choice to modify Speicher to obtain the invention as specified in the claim(s).

Response to Arguments

Applicant's arguments filed 1/19/05 have been fully considered but they are not persuasive. The argument that element number 34 in Schaer is not an electrode connector is not persuasive since element 34 is connected/joined/united to the electrode (figure 3), covers the electrode and prevents exposure of sharp edges of the electrode. The arguments that Schaer's connector is an insulator and the applicant's connector provides electrical and mechanical connection for the wire coil and may in some alternatives provide part of the electrode surface area and electrode length are not persuasive since those limitations are not claimed. It is noted that the features upon which applicant relies (i.e., electrical connection, provides part of the electrode surface area and length) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The argument that Speicher does not meet the functional use recitations in the claims is not persuasive since Speicher (or Schaer) provides a flexible electrode (column 5, line 46 and figures 2 and 3), a flexible lead that is intravascularly inserted/positioned in the patient (column 3, line 51), and that is approximately the same size, shape, and/or construction as the applicants invention. Therefore, Speicher (or Schaer) is capable of meeting the functional use recitations presented in the claims. In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.

Art Unit: 3762

See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Also, the examiner is not taking official notice and not relying on common knowledge in the art and therefore does not have to supply additional references to support the rejection as meeting the functional use recitations of the claims. The argument that Speicher's "about 3 mm" coil does not anticipate the claimed "about 2 mm" coil is not persuasive since the range of "about" has not been defined in the specification and since both Speicher's electrode and the applicant's electrode are flexible, implantable, about the same size, and are used for stimulation. The argument that reducing the size of Speicher's coil electrode to a diameter of "about 2 mm" would render the electrode of Speicher less satisfactory, or entirely unsatisfactory is not persuasive since reducing the electrode diameter of Speicher to about 2 mm would still allow Speicher's electrode to be in his intended electrode surface area range of 30-50 mm². The argument that Speicher's electrode is used to create maximum current density and the applicant's invention is used for low energy density is not persuasive since the fields created and/or energy source used to create the fields are not claimed.

Conclusion

This is a RCE of applicant's earlier Application No. 09/843051. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3762

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE
March 11, 2005

GEORGE R. EVANISKO
PRIMARY EXAMINER

3/11/05